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**UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA**

<p>UNITED STATES OF AMERICA, <i>ex rel.</i> John Doe</p> <p align="center">Plaintiffs,</p> <p align="center">v.</p> <p>UnitedHealth Group, Inc., UnitedHealthcare, Inc., Optum, and OptumRx</p> <p align="center">Defendants</p>	<p>RELATOR'S COMPLAINT PURSUANT TO THE FEDERAL FALSE CLAIMS ACT, 31 U.S.C. §§3729 ET SEQ.</p> <p>FILED UNDER SEAL</p> <p>DO NOT PLACE ON PACER</p> <p>CIVIL ACTION NO. <u>12</u> <u>4042</u></p> <p>JURY TRIAL DEMANDED</p>
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FILED**JUL 16 2012**

MICHAEL E. KUNZ, Clerk
By KIK Dep. Clerk

**RELATOR'S COMPLAINT PURSUANT TO
THE FEDERAL FALSE CLAIMS ACT, 31 U.S.C. §§ 3729 ET SEQ.**

Plaintiff ("Relator") brings this action on behalf of the United States of America to recover all damages, civil penalties and all other recoveries provided for under the Federal False Claims Act ("FCA").

I. THE PARTIES

1. Defendant UnitedHealth Group, Inc. ("UnitedHealth") is incorporated in Minnesota and is the largest managed care company, by revenue and membership, in the United States. UnitedHealth provides health insurance coverage for over 78 million people in all 50 states and the District of Columbia. Its revenues for 2011 were over \$100 billion. UnitedHealth is composed of two core businesses: UnitedHealthcare, Inc., which provides health benefits to its members, and Optum, which provides management and administrative services to United Health and UnitedHealthcare, Inc. UnitedHealth is named herein as a Defendant and to the extent its acts were performed or are otherwise attributable to any subsidiary or affiliate to it, then judgment should be entered against them where appropriate.

2. Defendant UnitedHealthcare, Inc., a wholly-owned subsidiary of UnitedHealth, is also incorporated in Minnesota. UnitedHealthcare, Inc., has a business unit known as UnitedHealthcare Medicare & Retirement, which had over \$34 billion in revenue in 2011 through its provision of a wide variety of Medicare insurance products including Medigap, Medicare Advantage plans (“MA’s”), Medicare Part D plans (“PDP’s”), and joint Medicare Advantage – Part D plans (“MA-PD’s”). These plans are offered to beneficiaries in all 50 states and the District of Columbia. In addition to UnitedHealthcare Medicare & Retirement, there is another business unit called UnitedHealthcare Community & State which manages state Medicaid benefits. UnitedHealthcare, Inc., is named herein as a Defendant and to the extent its acts were performed or are otherwise attributable to any subsidiary or affiliate to it, then judgment should be entered against them where appropriate.

3. Defendants UnitedHealthGroup, Inc., and UnitedHealthcare, Inc., are referred to collectively as “United.”

4. Defendant Optum is incorporated in Minnesota and is a wholly-owned subsidiary of UnitedHealth. Optum is composed of three key subsidiaries: OptumHealth, OptumInsight and OptumRx. Optum is named herein as a Defendant and to the extent the acts of Optum were performed or are otherwise attributable to any subsidiary or affiliate to it, then judgment should be entered against them where appropriate.

5. Defendant OptumRx (formerly known as Prescription Solutions) is based in Irvine, California, and provides pharmacy benefit management (“PBM”) services. These services include, among other things, administering and managing the Medicare Part D prescription drug benefits of millions of Medicare beneficiaries both within and without the United network of MA’s, PDP’s, and MA-PD’s. OptumRx’s revenues in 2011 topped \$19

billion. OptumRx is named herein as a Defendant and to the extent the acts of OptumRx were performed or are otherwise attributable to any subsidiary or affiliate to it, then judgment should be entered against them where appropriate.

6. Defendants Optum and OptumRx are referred to collectively as “Optum.”

7. All of the defendants named above are referred to collectively throughout this complaint as “Defendants.”

8. The United States is a plaintiff to this action. The United States brings this action on behalf of the Department of Health and Human Services, the Center for Medicare and Medicaid Services, and other federally funded health care programs including Medicare, TRICARE, Medicaid, etc.

9. Relator is a human being who has standing to bring this action pursuant to 31 U.S.C. §3730(b)(1). Relator's complaint is not based on any other prior public disclosures of the allegations or transactions discussed herein in a criminal, civil, or administrative hearing, lawsuit or investigation or in a Government Accounting Office or Auditor General's report, hearing, audit, or investigation, or from the news media.

II. SUMMARY OF THE ACTION

10. When a Medicare beneficiary applies for prescription drug benefits under Medicare Part D, the federal government sends a “Coordination of Benefits” (“COB”) form to the beneficiary’s PDP, or to the beneficiary’s MA-PD (this occurs when the beneficiary has Medicare Advantage and Medicare Part D coverage through the same insurer).¹ The COB form reflects, among other things, whether the beneficiary has private insurance. If so, the form

¹ The fraud in the instant case is equally applicable to United’s PDP’s and its MA-PD’s. To the extent this Complaint uses the term “PDP’s,” that term is meant to include both PDP’s and MA-PD’s.

provides sufficient information such that the private insurer can be billed when it is responsible for payment.

11. For each prescription drug provided to a beneficiary who has both private insurance and Part D coverage, there is a payer order, i.e., there are a set of rules which determine whether the private insurer or Part D is the primary payer. In many instances, Medicare is a subordinate payer to private insurers. In such situations, when a pharmacy bills a PDP for prescription drugs provided to a beneficiary, the PDP is not responsible for the vast majority of the bill. Rather, the private insurer is responsible.

12. From 2006 through the present, United has received millions of COB forms from the federal government which reflect that millions of United's Part D beneficiaries have active private health insurance coverage. However, Defendants' computer system fails to accurately download the information from the government. This results in United consistently being reflected as the primary payer when in fact the beneficiary's private insurer is the primary payer, i.e., United – and ultimately the federal government – routinely and as a matter of course paid bills for prescription drugs that should have been paid by private insurers.

13. This conduct has been ongoing since 2006. Defendants' employees, including Relator, have repeatedly raised this specific problem to the attention of their superiors, yet the problem has been ignored by Defendants. This has caused the federal government to pay millions of dollars in false claims.

III. JURISDICTION AND VENUE

14. Jurisdiction is founded upon the Federal False Claims Act (the "Act" or the "False Claims Act"), 31 U.S.C. § 3729 *et seq.*, specifically 31 U.S.C. § 3732(a) and (b), and also 28 U.S.C. §§ 1331, 1345.

15. Venue in the Eastern District of Pennsylvania is appropriate under 31 U.S.C. § 3732(a) in that, at all times material to this civil action, one or more Defendants transacted business in the Eastern District of Pennsylvania, or submitted or caused the submission of false claims in the Eastern District of Pennsylvania.

IV. THE FALSE CLAIMS ACT

16. The Federal False Claims Act (“FCA”), 31 U.S.C. §§ 3729-3733, provides, *inter alia*, that any person who (1) “knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval,” or (2) “knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim,” is liable to the United States for a civil monetary penalty plus treble damages. 31 U.S.C. § 3729(a)(1)(A)-(B).

17. The terms “knowing” and “knowingly” are defined to mean “that a person, with respect to information (1) has actual knowledge of the information; (2) acts in deliberate ignorance of the truth or falsity of the information; or (3) acts in reckless disregard of the truth or falsity of the information.” 31 U.S.C. § 3729(b)(1)(A)(i)-(iii). Proof of specific intent to defraud is not required. 31 U.S.C. § 3729(b)(1)(B).

18. The term “claim” means “any request or demand, whether under a contract or otherwise, for money or property and whether or not the United States has title to the money or property, that (1) is presented to an officer, employee, or agent of the United States; or (2) is made to a contractor, grantee, or other beneficiary, if the money or property is to be spent or used on the Governments behalf or to advance a Government program or interest, and if the United States Government (a) provides or has provided any portion of the money or property requested or demanded; or (b) will reimburse such contractor, grantee, or other beneficiary for any portion of the money or property which is requested or demanded” 31 U.S.C. § 3729(b)(2)(A)(i)-(ii).

19. “[T]he term ‘material’ means having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property.” 31 U.S.C. § 3729(b)(4).

V. THE MEDICARE PART D PROGRAM

A. Overview

19. On December 8, 2003, Congress enacted the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (the "MMA"). Title I of the MMA created new outpatient prescription drug coverage under Medicare known as "Medicare Part D."

20. Part D went into effect on January 1, 2006. The program is administered by the United States Department of Health and Human Services, Centers for Medicare and Medicaid Services ("CMS").

21. Part D coverage is offered through private insurance carriers known as PDP's.² To administer Medicare Part D drug benefits, a PDP submits a certified application to CMS and awaits a determination from CMS that it is a qualified sponsor. 42 C.F.R. § 423.505.

22. If CMS approves a PDP, the PDP must enter into a contract containing specific provisions and certifications. 42 C.F.R. § 423.505. The term of the contract is twelve (12) months, which the PDP can renew annually. 42 C.F.R. § 423.506(a)-(c).

23. PDP's typically enters into agreements with PBM's to assist in administering Part D drug benefits to beneficiaries. PBM's provide various administrative and management services, including the receipt and processing of prescription drug claims from pharmacies.

B. Part D Payment Process and PDP Submissions

1. Annual Bids and Direct Subsidies

24. A PDP receives most of its revenue through payments from CMS. The remainder of a PDP's income comes from premiums that are paid directly by beneficiaries.

² Defendant United owns and operates numerous PDP's and MA-PD's.

25. To qualify for CMS payments, a PDP must submit a bid to Medicare Part D. 42 C.F.R. § 423.265. The bid contains a per-member, per-month ("PMPM") cost estimate for providing prescription drug benefits to an average Medicare beneficiary in a particular geographic area. The bid also includes the PDP's estimated administrative costs and return on investment. 42 C.F.R. § 423.265(c). From the PDP bids, CMS calculates nationwide and regional benchmarks which represent an average PMPM cost.

26. If a PDP's bid is accepted, CMS gives the PDP advance monthly payments consisting of the PDP's "direct subsidy" per enrollee (which is based on the bid), estimated reinsurance subsidies for catastrophic coverage, estimated low-income subsidies, and, at the end of the year, certain "risk corridor" payments. 42 C.F.R. §§ 423.315; 423.329.

2. Prescription Drug Event Reports

27. As a condition of payment, each time a Medicare Part D beneficiary gets a prescription filled under Part D, the PDP notifies CMS of the event, including the cost the PDP has incurred. 42 C.F.R. § 423.322. More specifically, when a pharmacy dispenses a drug to a Medicare Part D patient, it submits a claim which includes the ingredient cost (the cost of the drug itself), a dispensing fee, and any sales or similar taxes paid, less any payments received from the patient. CMS is then notified of the transaction – known as a Prescription Drug Event ("PDE") – including the amount paid to the pharmacy by a PDP.

28. Importantly, CMS uses the PDE information at the end of the payment year when it reconciles its advance payments to the PDP with the costs the PDP has incurred throughout the year.

29. As noted above, most PDPs (including Defendant United) use a PBM (in this case, United uses Defendant Optum Rx) to process incoming claims from pharmacies. Claims typically undergo several near-instantaneous adjustments between these parties before the plan

finally adjudicates a claim for payment. The PDE is a summary record that documents the final adjudication of a claim.

3. Direct/Indirect Remuneration Reports; the Reconciliation Process

30. At year end, CMS goes through a reconciliation process with each PDP. In the reconciliation process, PDPs are required to report their direct and indirect remuneration ("DIR") for the plan year to CMS. 42 C.F.R. § 423.343. DIR consists of discounts, rebates, and other price concessions on drugs that lower the PDP's net costs. The year-end totals include actual DIR and estimated DIR that the plan sponsor expects to receive after the reporting date.

31. The reconciliation process compares the monthly advance payments made to the PDP throughout the year with the cost data submitted by PDP's through PDE records and DIR data. The purpose of the reconciliation process is to determine if any additional payments are required by CMS to the PDP, or if any payments are required from the PDP to CMS. Stated simply, if it is determined that CMS underpaid the PDP, CMS typically pays the difference to the PDP. 42 C.F.R. § 423.336(b)(2). Contrariwise, if CMS overpaid the PDP for its costs, it typically recoups the overpayment from the PDP. 42 C.F.R. § 423.336(b)(3).

32. More specifically, after CMS reconciles a plan's low-income subsidy and reinsurance costs, it then determines risk-sharing amounts owed by the plan to CMS or by CMS to the PDP related to the PDP's bid. Risk-sharing amounts involve calculations based on whether and to what degree a plan's allowable costs per beneficiary exceeded or fell below a target amount for the plan by certain threshold percentages (commonly called the Part D "risk corridor"). 42 C.F.R. § 423.336.

33. From 2006 to 2011, the Part D risk corridors were set by statute:

2006 to 2007 Risk Corridors

Difference between target amount and plan's allowable risk-corridor costs	Medicare	Sponsor
Greater than 5% loss	Pays 80%	Pays 20%
Greater than 2.5% but less than or equal to 5% loss	Pays 75%	Pays 25%
Within 2.5% of target	n/a	Plan bears 100% of loss or retains 100% of profit
Greater than 2.5%, but less than or equal to 5% profit	Medicare recoups 75%	Plan retains 25%
Greater than 5% profit	Medicare recoups 80%	Plan retains 20%

2008 to 2011 Risk Corridors

Difference between target amount and plan's allowable risk-corridor costs	Medicare	Sponsor
Greater than 10% loss	Pays 80%	Pays 20%
Greater than 5% but less than or equal to 10% loss	Pays 50%	Pays 50%
Within 5% of target	n/a	Plan bears 100% of loss or retains 100% of profit
Greater than 5%, but less than or equal to 10% profit	Medicare recoups 50%	Plan retains 50%
Greater than 10% profit	Medicare recoups 80%	Plan retains 20%

C. Medicare Part D Plan Certifications

34. Medicare Part D regulations require that the contract between a PDP and CMS contain the following provisions:

- a) the PDP must comply with "Federal laws and regulations designed to prevent fraud, waste, and abuse, including but not limited to applicable provisions of . . . the False Claims Act. " 42 C.F.R. § 423.505(h)(1); and
- b) as a condition for receiving monthly payment, the PDP agrees that its Chief Executive Officer, Chief Financial Officer or individual delegated the authority to sign on behalf of one of these officers certify the accuracy, completeness, and truthfulness of all data that CMS specifies, including but not limited to claims data and bid submission data. 42 C.F.R. § 423.505(k).

35. Medicare Part D regulations also require PDP's to make the following certifications regarding its requests for reimbursement:

(a) "as a condition for receiving a monthly payment," the PDP must request payment under the contract on a document that certifies the accuracy, completeness, and truthfulness of all data, including claims data, bid submission data, and other data that CMS specifies, related to payment. 42 CFR § 423.505(k)(1);

(b) "the information CMS relies on in determining payment is accurate, complete, and truthful and acknowledge that this information will be used for the purposes of obtaining Federal reimbursement." 42 CFR § 423.505(k)(2); and

(c) "the claims data it submits . . . are accurate, complete, and truthful and acknowledge that the claims data will be used for the purpose of obtaining Federal reimbursement." 42 CFR § 423.505(k)(3).

36. In addition, and as noted above, PDP's are required to submit annual bids to CMS containing cost information supporting the basis for the bid submission. In connection with these annual bids, the PDP sponsors certify that the information provided was accurate, complete and truthful. 42 CFR §423.505(k)(4).

37. Also as noted above, each and every time a pharmacy submits a claim, the PDP notifies CMS of the claim, including the amount it has paid to the pharmacy for that claim. In order for claims data to be accepted by the government's Prescription Drug Front End Processing System ("PDFS"), and the Drug Data Processing System ("DDPS"), the PDP submitting the claim must first pass a claims certification process. The first part of the certification process entails executing and submitting an Electronic Data Interchange ("EDI") Agreement and Submitter Application to CMS. The EDI Agreement states:

By signing below, the eligible organization certifies that each submission of PDE data pursuant to this Agreement will be accurate and complete to the eligible organization's best knowledge, information and belief.

38. The EDI Agreement also requires the PDP sponsor to certify that it acknowledges "that all claims will be paid from Federal funds, that the submission of such claims is a claim for payment under the Medicare program."

39. In addition, in their submissions to CMS, PDP's provide PDE/DIR Attestations, stating that to the best of their knowledge, the information submitted by the PDP's is accurate, complete and truthful. Specifically, the attestations state:

[w]ith regards to the information described in the above paragraphs, the Part D Organization attests that it has required all entities, contractors, or subcontractors, which have generated or submitted said information (PDE and DIR data) on the Part D Organizations behalf, to certify that this information is accurate, complete, and truthful based on their best knowledge, information and belief.

40. The PDE/DIR Attestations also state: "The Part D Organization acknowledges that the information described in the above paragraphs will be used for the purposes of obtaining federal reimbursement and that misrepresentations or omissions in information provided to CMS may result in Federal civil action and/or criminal prosecution."

D. The Medicare Secondary Payer Law

41. In administering Part D benefits, both PDP's and PBM's must comply with the Medicare Secondary Payer law ("MSP"). The MSP is designed to reduce Medicare costs by making the government a secondary payer when a beneficiary has other sources of primary insurance. The statute provides that a Medicare payment "may not be made . . . with respect to any item or service to the extent that payment has been made or can reasonably be expected to be made" by a private insurer. 42 U.S.C. § 1395y(b)(2)(A). The regulations implementing the MSP are even more explicit: "CMS does not pay for services to the extent Medicare is not the primary

payer under section 1862(b) of the Act and part 411 of this chapter.” 42 C.F.R. § 422.108(a).³

Moreover, Medicare providers such as United:

must, for each MA plan --

- (1) Identify payers that are primary to Medicare under section 1862(b) of the Act and part 411 of this chapter;
- (2) Identify the amounts payable by those payers; and
- (3) Coordinate its benefits to Medicare enrollees with the benefits of the primary payers, including reporting, on an ongoing basis, information obtained related to requirements in paragraphs (b)(1) and (b)(2) of this section in accordance with CMS instructions.

42 C.F.R. § 422.108(b)(1)-(3).

42. Although the language quoted above speaks to MA plans, it applies to PDP’s and MA-PD’s such as those owned and operated by United. Specifically, when Part D was passed into law, the MSP regulations were amended to state that:

[t]he provisions of 42 C.F.R. § 422.108 of this chapter regarding Medicare secondary payer procedures apply to Part D sponsors and Part D plans (with respect to the offering of qualified prescription drug coverage) in the same in the same way as they apply to MA organizations and MA plans under Part C of title XVIII of the Act, except all references to MA organizations and MA plans are considered references to Part D sponsors and Part D plans.

42 C.F.R. §423.462.

43. On a substantive level, the MSP provides that, in many situations, Medicare is the secondary payer rather than primary payer for prescription drugs provided under Part D. More specifically, under the MSP, Medicare is precluded from, *inter alia*, making payment for drugs to the extent that payment has been made or can reasonably be expected to be made by a private insurer, promptly, under the conditions summarized below:⁴

³ Section 1862(b) of the Act refers to the Medicare Secondary Payer (MSP) provisions of the Social Security Act. See also CMS, Medicare Prescription Drug Benefit Manual, Chapter 14 - Coordination of Benefits.

⁴ If the existence of other insurance coverage is unknown or when another source is obligated to pay but is not expected to pay promptly, the MSP allows a PDP to make a conditional payment to cover medical expenses. 42

If the patient	And this conditions exists	Primary Payer	Secondary Payer
Is age 65 or older, and is covered by a Group Health Plan through current employment or spouse's current employment	The employer has less than 20 employees	Medicare	Group Health Plan
Is age 65 or older, and is covered by a Group Health Plan through current employment or spouse's current employment	The employer has 20 or more employees, or at least one employer is a multi-employer group that employs 20 or more individuals	Group Health Plan	Medicare
Has an employer retirement plan and is age 65 or older	The patient is entitled to Medicare	Medicare	Retiree coverage
Is disabled and covered by a Group Health Plan through his or her own current employment or through a family member's current employment	The employee has less than 100 employees	Medicare	Group Health Plan
Is disabled and covered by a Group Health Plan through his or her own current employment or through a family member's current employment	The employee has 100 or more employees, or at least one employer is a multi-employer group that employs 100 or more individuals	Group Health Plan	Medicare
Has End-Stage Renal Disease and Group Health Plan Coverage	Is in the first 30 months of eligibility or entitlement to Medicare	Group Health Plan	Medicare
Has End-Stage Renal Disease and Group Health Plan Coverage	After 30 months	Medicare	Group Health Plan
Has End-Stage Renal Disease and COBRA Coverage	Is in the first 30 months of eligibility or entitlement to Medicare	COBRA	Medicare
Has End-Stage Renal Disease and COBRA Coverage	After 30 months	Medicare	COBRA
Is covered under Workers' Compensation because of a job-related illness or injury	The patient is entitled to Medicare	Workers' Compensation (for health care items or services related to job-related illness or injury) claims	Medicare
Has been in an accident or other situation where no-fault or liability insurance is involved	The patient is entitled to Medicare	No-fault or liability insurance for accident or other situation related health care services claimed or released	Medicare
Is age 65 or older OR is disabled and covered by Medicare and COBRA	The patient is entitled to Medicare	Medicare	COBRA

E. Coordination of Benefits

43. When a beneficiary enrolls in Part D, they are required to fill out a Coordination of Benefits ("COB") form and submit the form to CMS. The COB form requires, *inter alia*, the beneficiary to identify whether the beneficiary has private health insurance. When CMS receives

C.F.R. § 411.50. In such circumstances, the PDP must subsequently seek payment from the primary payer, and reimburse CMS for the conditional payment it made. 42 U.S.C. § 1395y(b)(2)(B)(i)-(ii).

COB forms from beneficiaries, CMS transmits the information on the COB forms to the beneficiary's PDP (in this case, to United's mainframe computer) through a system known as ConnectDirect. CMS typically "batches" this COB information, i.e., CMS does not normally send a single beneficiary's COB information to a PDP. Rather, CMS will send, to a PDP such as United, COB information for 10-20 beneficiaries at a time.

44. As demonstrated in the chart above, in many instances, if a beneficiary has private insurance, the private insurer is the "primary payer," whereas in other instances, even if a beneficiary has private insurance, Part D is the primary payer, and the private insurer is the "secondary payer."

45. For example, suppose that a beneficiary has private insurance, and further assume that for the prescription in question, the Part D rules provide that the private insurer is primary, and the PDP is secondary. When the beneficiary goes to a pharmacy for a prescription, the private insurer will be billed by the pharmacy and will pay the covered amount. If there is any amount that remains to be paid, the PDP will be billed and will pay the covered amount.

46. Therefore, for obvious reasons, COB information is critical to determining which payer is primary and which is secondary, i.e., the "payer order." Thus, under the statutes and regulations cited above, PDP's are required to obtain and process COB information accurately, so that the payer order is correct. United does not dispute this obligation in its internal training materials:

When CMS sends PRM (primary) COB information to the plan, the plan must update the member record to indicate other primary insurance coverage exists.

47. If the payer order is incorrect – that is, if the PDP is listed as primary when in fact the primary payer should be a private insurer – the government ultimately pays a bill that should have been paid by a private insurer.

VI. THE FRAUDULENT SCHEME

A. The Fundamental Failure to Process COB Data

48. Relator was hired by United in early 2012. The accurate processing of COB information from CMS to all of United's PDP's – that is, making sure that the information received from CMS regarding payer order is properly loaded and administered for tens of millions of people – is central to the Relator's work responsibilities.

49. One of Relator's supervisors is Nichole Brindle (Director of Medicare & Retirement Pharmacy Operations). Brindle's immediate supervisor is Michelle Renaud (Vice President of Pharmacy Operations).⁵

50. Shortly after starting work for United, Relator began to realize that something was drastically wrong with United's COB processing. Specifically, Relator observed that United's PDP's were paying claims that should have been paid by private insurers, i.e., United was paying as the primary payer in situations where, under the Medicare Secondary Payer Law, the beneficiaries' private insurer was primary and the PDP was secondary.

51. Relator later discovered that Defendants, each and all, knew that, due to Defendants' actions and failures to act, the government was consistently paying huge volumes of claims which should have been submitted to, and paid for, by private insurance companies. In order to understand Defendants' fraudulent scheme, some background on Defendants' COB processing system is necessary.

52. Defendant Optum serves as United's PBM and as such administers claims received from pharmacies. In this capacity, Defendant Optum has been engaged by United to assist United in the creation and/or maintenance of United's COB computerized processing

⁵ Brindle and Renaud have worked for United for many years, and have been materially involved in United's Medicare Part D pharmacy operations since United became a provider of prescription drug benefits under Medicare Part D in 2006.

system (the “System”). Employees from United’s Pharmacy Operations Group (the group within which Relator works) and the corresponding business unit within Optum interact on a daily basis with respect to COB information received from CMS.

53. One business tool used by the two groups is known internally as the “Optum Issues Log.” This is a log maintained by the two groups which was and is used to identify and ensure the resolution of issues related to COB information received from CMS. The Optum Issues Log was a part of the agenda during weekly conference calls involving the United COB team and the Optum COB team.

54. Up until June 6, 2012, Bridget M. Rodine worked for Optum as a “Client Manager.” Her job was to serve as a liaison between United and Optum with respect to, *inter alia*, COB issues. As of this writing, Raymond McTague and Cristal Perea work for the Optum COB team and are responsible for fixing problems placed on the Optum Issues Log. All of these individuals regularly attended the weekly conference calls.⁶

55. As for United, the Optum Issues Log was primarily Tracy Kenney and Relator's responsibility to maintain, update and manage. Relator first became familiar with the Optum Issues Log in early 2012 when he began attending the weekly teleconference calls. Through the training provided by United and by his direct participation in the weekly conference calls, Relator became aware that the System was fundamentally flawed. Specifically, Relator was informed by his predecessor, Tracy Kenney, that prior to Relator’s arrival, Ms. Kenney had repeatedly observed that the System was failing on a routine and consistent basis to accurately load COB information received from CMS.

⁶ In addition, Optum employees Luanne Contla, Julie Parkins, Jacquelyn Panis, Suzanne Gardner and Kathy Hall worked on the COB issues identified on the Optum Issues Log, and often attended the weekly conference calls.

56. Ms. Kenney further stated that the failure was causing United to be the primary payer in thousands if not millions of situations where the primary payer should have been the private insurer identified in the COB information provided by CMS to United.

57. Finally, Ms. Kenney stated that she had identified this issue to United and Optum in 2010, had placed the issue on the written Optum Issues Log multiple times, and had discussed the problem and its significance on numerous occasions with Optum employees, including but not limited to Brigitte Rodine, Raymond McTague and Cristal Perea, and that these employees had admitted that the System was fundamentally flawed with respect to processing COB information received from CMS.

58. To prove her point, with Relator observing live through a screen-sharing tool, Ms. Kenney accessed the System's beneficiary database and selected a beneficiary at random. The System showed that CMS had provided United with the beneficiary's current and active private insurance information, yet the System had the same member's Other Health Insurance ("OHI") field listed as "inactive." Ms. Kenney explained that this was due to the System's inability to accurately load COB information received from CMS. Even when Kenney manually reset the member's OHI field to active (to prevent Medicare from paying as primary in situations where Medicare was secondary), the System refused to acknowledge the change and continued to list the member's OHI field as inactive. Thus, any claims submitted by pharmacies to United for this beneficiary were paid by United as primary payer (and ultimately, by the government for the reasons discussed above and below), even in situations where United was the secondary payer.

59. In such situations (as detailed in the chart cited on page 13), the beneficiary's private insurer should have paid the bill. This is but one of the countless scenarios where COB

information was excluded from loading correctly or was inactivated by the System. As noted above, this issue was repeatedly raised by Relator and others, yet nothing changed.

60. Another example of this problem manifested itself with respect to the beneficiaries in a United PDP known as “Pulse.” It was noted that the COB information from CMS for a large sector of beneficiaries had not properly loaded on the System. Optum subsequently stated that the loading was remedied, yet when the COB fields were later examined, it was found that the problem had not been resolved and had continued to exist. The issue was again raised, Optum again claimed they fixed the problem, and again a review showed that the problem had not been remedied.

61. When Relator assumed Ms. Kenney’s position, he continued to raise these the failure of the System to capture private insurance data, both to United and Optum, such that the issue continued to be on the Optum Issues Log and continued to be discussed on the weekly conference calls. Relator can state that in April or May 2012, he was discussing his frustration with Brigitte Rodine (a Client Manager for Optum). Ms. Rodine stated that she had repeatedly explained the problem to her superiors, and she was frustrated because they refused to properly address this overarching and fundamental flaw.

62. Relator can state that when he personally began addressing the problem, Optum made various nonsensical excuses for the failures. Subsequently, the leader of the Optum COB team, Ray McTague, eventually admitted to Relator that “logic was flawed” in the System, such that the COB information from CMS which reflected active private insurance was not properly loading into the System, and United was subsequently paying bills as the primary payer, on a routine and system-wide basis, when the true primary payers under the MSP were private insurers.

63. Through subsequent investigation, Relator ascertained that Defendants' failure to add private insurance information to the System was nationwide. For example, Relator learned that the logic flaw extended throughout the System – including to all United PDP plans and United MA-PD plans – and thus affected United's entire Medicare population, nationwide. Moreover, Relator learned that Optum utilized the same flawed System for its non-United customers, i.e., the COB logic flaw extended to all PDP's and MA-PD's serviced by Optum, including other plans outside of the United umbrella.

64. Relator's investigation revealed that in order to work, the System required the COB information to be formatted in a very particularized way when it was transmitted by CMS. If the information was not precisely formatted, the System placed United as the primary payer, even when beneficiaries had active private insurance which should have been primary. More specifically, Relator's investigation revealed that in order for the System to properly load COB data, the transmission from CMS had to contain a table of information referred to as "4-Rx data." If the CMS transmission did not contain the data in the correct format, the System rejected the information regarding the beneficiary's private insurance and instead placed United first in the payer order, including in thousands if not millions of situations where private insurers should have been the primary payer.

65. Relator sought to understand the frequency of the problem by questioning his supervisor at United, Nichole Brindle (Director of Pharmacy Operations). Brindle, who had direct access to the transmissions of COB data from CMS and United's processing of same, informed Relator that in 90% of transmissions, an important portion of the 4Rx data was missing (or was otherwise not formatted properly), and in such situations, the System placed United first in the payer order, instead of the beneficiary's private insurer.

66. In May 2012, Brindle raised the issue during a meeting that included Relator and two other United employees (Joseph Magann and Lavita Burroughs). With Relator looking at the screen display in the Ocean City conference room in United's Horsham, PA facility, Brindle accessed the System's beneficiary database and selected a beneficiary at random. United's eligibility database listed the beneficiary as having active private insurance, yet the System showed the members' COB as "inactive," which left United as the primary payer for all claims submitted by pharmacies, including situations where the private insurer was the primary payer under the MSP. Brindle then selected another beneficiary at random and found the same scenario.

67. Brindle agreed with Relator's assessment that the logic flaw was causing untold numbers of incorrect payments, i.e., any claims submitted by pharmacies to United for such beneficiaries were paid by United as primary, despite many instances where the private insurers were first in the payer order.

68. The blatant nature of the problem led to its placement on a second troubleshooting list known as the Optum/United Health "Eligibility Issues Log." This log was designed to address issues related to eligibility. A weekly conference call was held to discuss these issues. The Optum employees primarily responsible for these issues included Jaqueline Panis, Luanne Contla and Julie Parkins. Relator, Tracy Kenney, Lavita Burroughs, Krista Hoolihan, Jen Haglund, Dave Cruz, Ravi Perumalsamy, and Joseph Magann often attended the calls for United.

69. Relator can state that in response to his inquiries regarding the COB logic flaw, he received a series of vague or misleading answers from Optum, including "we haven't identified a [software] developer who can fix the problem," "we still haven't gotten a developer," "we are working with IT and a developer to fix the flaw," "we will call the developer this afternoon and

have update for you later,” “the developer did not tell us what wanted to find out so will have to talk to him again,” “developer is offshore, so will talk to him later,” “working with another IT perosn and still have to talk to offshore developer,” and “talk to your supervisor (Brindle); she recently visited our headquarters in California so she knows just as much as we do on this issue,” etc.⁷

70. When Relator sought to grasp the temporal scope of the problem, he questioned Cristal Perea, one of Optum’s “point people” with respect to processing COB transmissions received from CMS. Perea, who has worked at Optum since the mid-2000’s, informed Relator that the COB primary/secondary payer logic flaw dated back to the System’s initial Part D launch in 2006, and that the problem has been occurring consistently for the last six years.⁸

71. Relator’s investigation further revealed an even simpler but perhaps more fundamental problem with the System. CMS typically transmits COB data to United in batches, e.g., up to 20 beneficiary records at a time. However, Relator learned that the System was designed to accept a maximum of 8 records per COB transmission from CMS. In United’s words, the System “only has the ability to load 1 PRM (primary record) and 7 SUP (supplemental records) but CMS can send up to 20 records.”

72. Thus, even if the COB transmission somehow arrived in a perfect and loadable format, a maximum of 1 primary record and 7 supplemental records would be properly loaded.

⁷ Around this time, Brindle travelled to Optum’s headquarters in Irvine, California, presumably to address the COB logic flaw and/or other issues with the Optum team. Curiously, upon her return, Brindle began a campaign to derail Relator’s investigation into the COB logic flaw. Subsequently, she began to retaliate against him.

⁸ Perea further stated that she was in possession of documents which proved that the System had been failing for this length of time. When Relator requested the documents, Perea agreed to provide them, but subsequently refused to do so, citing supervisory orders to keep the documents confidential.

The remainder of the private insurance data would not be loaded, and United, again, would be listed as primary in the payer order for all of these beneficiaries.⁹

73. The fundamental failure to process COB data has resulted in an additional problem – so-called “N1 Mismatches” – which highlights Defendants’ scienter.

74. When a beneficiary goes to a pharmacy for the first time, they are typically asked to provide information regarding any insurance they have (whether private insurance, Part D, or both). When a beneficiary has both, the pharmacy loads that information into its point-of-service (“POS”) billing system, which, from the pharmacy counter, is linked to virtually all private insurers and all PDP’s, including United. Assuming United had properly loaded the beneficiary’s COB data from CMS, the primary payer would pay first.

75. However, as described above, approximately 90% of the time, the COB data for United beneficiaries had not been properly loaded, and thus United was listed as the primary payer when in fact the primary payer should have been the beneficiary’s private insurer. This results in United – and ultimately the government, for the reasons explained below – to pay a bill that it should not have paid.

76. Such discrepancies at the pharmacy counter – e.g., the beneficiary has presented a private insurance card but the POS system reflects no private insurance – are known as “N1 Mismatches.” CMS – through the CMS TrOOP Facilitator – notifies the PDP (in this case, United) of the mismatch. Due to the frequency of Defendants’ failures to properly load COB data, this happens often, i.e., Defendants consistently received, on a monthly basis, thousands of electronic reports of N1 Mismatches from CMS.

⁹ Moreover, Relator can state that if a beneficiary’s COB information survives the gauntlet that was and is the System, if the beneficiary subsequently switched from one United Plan to another, the beneficiary’s COB data did not follow them, and thus the COB process and logic flaw repeated itself, with an identical error rate.

77. When Defendants received N1 Mismatch Reports they “batched” them into a monthly report that was issued on the 10th of each month. This report was supposed to be sent to a particular United department. That department was supposed to send letters to the beneficiaries who were the subject of the N1 Mismatches, so that United could determine what private carrier insured the beneficiary. The responses to the letters from beneficiaries were then supposed to be sent to the “Enrollment Group” so that the updated private insurance information could be loaded into the System, and so that United could recoup its – or rather, the government’s – losses.

78. While this process may make some sense analytically, Defendants failed to follow the process. Often, the N1 Mismatch Reports were not issued for many months, and when they were issued, they were often sent to the wrong mailing address, where they sat unviewed and unused.

79. For other significant stretches of time, even if the Mismatch Report was sent and received, Defendants simply did not send the letters.¹⁰

80. In other situations, United attempted to generate the letters, but the text of the letters was changed in a manner which prohibited the System from printing the letters.

81. If and when letters were actually sent, if the data was not entered in the manner required by the System, the private insurance information would still not be reflected in the System, and the same series of problems would recur. As noted by one United supervisor “I have been told in some cases it takes [the System] a year or more to resolve” N1 Mismatches.

¹⁰ This conduct was paralleled by a similar failure. United is legally required to periodically survey its beneficiaries to obtain information regarding any private insurance they might have. United routinely ignores this obligation, and thus in many instances, United pays bills for beneficiaries who have private insurance which is primary.

B. The Failure to Subrogate

82. In certain instances, Part D rules provide that a PDP may conditionally pay a claim as if the PDP is primary, even if the primary payer should be a private insurer. In such situations, the law requires the PDP – here, United – to pursue the private insurer for payment through subrogation.

83. United has an internal computer system known as the Next Generation Policy System (“GPS”). This is United’s system for housing beneficiaries’ eligibility data across the United platform of insurance coverage, including but not limited to PDP’s and MA-PD’s.

84. United owns and administers scores of MA-PDs and PDP’s. Some of these plans utilize GPS. Within United, these plans are known as “migrated plans,” i.e., plans which have migrated to the GPS platform. Plans which do not utilize GPS are known as “non-migrated plans.”

85. Relator can state that the non-migrated plans operated by United – both PDP’s and MA-PD’s – have no process in place to pursue subrogation. From 2006 through the date of this writing, these non-migrated plans simply do not pursue private insurers for payment – period – despite a legal obligation to do so. Thus, United pays the bills for prescriptions which should have been paid for by private insurers through the subrogation process. These non-migrated plans include but are not limited to Sierra Nevada, Wellmed Citrus PHC/CHC, and Community and State (which also includes Medicaid), and, from 2006 through 2010, both the COSMOS and NICE plans.¹¹

86. Relator can further state that the PDP’s and MA-PD’s which actually made the migration to GPS also completely failed to pursue subrogation from 2006 through early 2010. This aspect of the scheme, alone, has cost the government many millions on dollars.

¹¹ These two plans, which account for approximately 2.5 million beneficiaries, migrated to GPS in 2010.

87. In early 2010, in apparent recognition of its legal obligation to do so, United mailed subrogation letters to a select group of insureds in certain migrated plans. Specifically, 445,239 people were sent subrogation letters. The purpose of the letters was to verify the beneficiary's private insurance so that United could seek payment from those private insurers in instances where United made a conditional payment, but in fact the private insurer was primary and should have paid.

88. United received 221,715 responses. A significant subset of those respondents were subsequently determined to have private insurance which was primary with respect to the claims in question. Notwithstanding direct evidence that these private insurers were primary, and notwithstanding United's clear legal obligation to collect these monies and remit them to the government, as of this writing, United has done nothing with respect to these claims.

VII. DEFENDANT'S FALSE CLAIMS

87. To qualify as a CMS-approved PDP, and to re-qualify for subsequent years, United certified to CMS in its contracts that it agreed to comply with "[f]ederal laws and regulations designed to prevent fraud, waste, and abuse, including but not limited to applicable provisions of . . . the False Claims Act." 42 C.F.R. § 423.505(h)(1).

88. In its application to become a CMS-approved PDP, and to re-qualify for subsequent years, United made the following certifications of data as conditions of payment:

(a) data, including claims data, bid submission data, and other data that CMS specifies, related to payment is accurate, complete and truthful. 42 CFR § 423.505(k)(1);

(b) "the information CMS relies on in determining payment is accurate, complete, and truthful and acknowledge that this information will be used for the purposes of obtaining Federal reimbursement." 42 CFR § 423.505(k)(2);

(c) "the claims data it submits . . . are accurate, complete, and truthful and acknowledge that the claims data will be used for the purpose of

obtaining Federal reimbursement. If the claims data are generated by a related entity, contractor, or subcontractor of a Part D plan sponsor, the entity, contractor, or subcontractor must similarly certify . . . the accuracy, completeness, and truthfulness of the data and acknowledge that the claims data will be used for the purposes of obtaining Federal reimbursement.” 42 CFR § 423.505(k)(3); and

(d) in connection with its annual bids, United certified that the information provided was accurate, complete and truthful. 42 CFR §423.505(k)(4).

89. United also certified in its PDE/DIR reports submitted to CMS that the information was accurate, complete, and truthful based on its knowledge, information and belief.

90. These certifications, which were conditions of payment, were false because United knowingly violated the MSP statutes and regulations by paying bills which should have been paid by private insurers, and by submitting inaccurate, incomplete and false data to CMS.

91. This data included payments from United to pharmacies for claims which should, by law, have been paid by private insurers; yet, United certified that it properly paid the claims in question. These purported costs were included by United in both the look-back reconciliation process, and in the look-forward bidding process, thus causing the government to pay for prescriptions for which the government was not financially responsible.

92. Moreover, in reliance on the representations and information United provided, CMS has repeatedly certified United PDP’s and MA-PD’s as eligible Part D sponsors.

93. Had United not falsely certified to the conditions referred to herein, CMS would not thereafter have re-certified United and thus would not have made any of the payments it made to United.

COUNT I
Federal False Claims Act
31 U.S.C. §3729(a)(1)[1986] and
31 U.S.C. §3729(a)(1)(A)[2009]

94. Relator repeats and re-alleges each and every allegation contained in the paragraphs above as though fully set forth herein.

95. Defendants knowingly submitted and caused the submission of false or fraudulent claims for payment or approval for drugs to officials of the United States Government in violation of 31 U.S.C. §3729(a)(1)[1986], and 31 U.S.C. §3729(a)(1)(A)[2009].

96. By virtue of the false or fraudulent claims that Defendants presented, the United States has suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT II
Federal False Claims Act
31 U.S.C. §3729(a)(1)(B)[2009]

97. Relator repeats and re-alleges each and every allegation contained in the paragraphs above as though fully set forth herein.

98. Defendants knowingly made, used or caused to be made or used, false records or statements material to false or fraudulent claims to the United States Government, in violation of 31 U.S.C. §3729(a)(1)(B)[2009].

99. By virtue of the false or fraudulent claims that Defendants caused to be presented, the United States has suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

PRAYER FOR RELIEF

WHEREFORE, Relator, on behalf of the United States, demands that judgment be entered in his favor and against Defendants for the maximum amount of damages and such other relief as the Court may deem appropriate on each Count. This includes, with respect to the

Federal False Claims Act, three times the amount of damages to the Federal Government plus civil penalties of no more than Eleven Thousand Dollars (\$11,000.00) and no less than Five Thousand Five Hundred Dollars (\$5,500.00) for each false claim, and any other recoveries or relief provided for under the Federal False Claims Act.

Further, Relator requests that he receive the maximum amount permitted by law of the proceeds of this action or settlement of this action collected by the United States, plus reasonable expenses necessarily incurred, and reasonable attorneys' fees and costs. Relator requests that his award be based upon the total value recovered, both tangible and intangible, including any amounts received from individuals or entities not parties to this action.

Dated: July 16, 2012

Respectfully submitted,

BERGER & MONTAGUE, P.C.

A handwritten signature in black ink, appearing to read "Dan Miller", is written over a horizontal line.

Daniel R. Miller (PA Bar No. 68141)

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Court Name: EDPH-Philadelphia
Division: 2
Receipt Number: PPE066267
Cashier ID: stomas
Transaction Date: 07/16/2012
Payer Name: BERGER AND MONTAGUE P.C.

CIVIL FILING FEE
For: BERGER AND MONTAGUE P.C.
Case/Party: 0-PPE-2-12-CV-04042-001
Amount: \$350.00

PAPER CHECK CONVERSION
Remitter: BERGER AND MONTAGUE P.C.
Check/Money Order Num: 181306
Amt Tendered: \$350.00

Total Due: \$350.00
Total Tendered: \$350.00
Change Amt: \$0.00

Only when bank clears the check,
money order, or verifies credit of
funds is the fee or debt officially
paid or discharged. A \$45 fee will
be charged for a returned check.